IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: | Quing Zhu | ) |
| | | ) Group Art Unit: 3737 |
| Serial No.: | 10/764,268 | ) |
| | | ) |
| Filed: | January 23, 2004 | ) |
| | | ) Examiner: Cwern |
| | | ) Johnathon |
| For: | METHOD OF MEDICAL IMAGING | ) |
| | USING COMBINED NEAR INFRARED DIFFUSIVE | ) |
| | LIGHT AND ULTRASOUND | ) |

## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Via EFS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


In response to the Final Office Action mailed November 14, 2007, and in conjunction with the Notice of Appeal filed concurrently herewith, the Applicants submit the following remarks in support of the Pre-Appeal Brief Request for Review:

## REMARKS

Claims 1–17 are pending in the present application. No claims have been added, cancelled or amended, leaving Claims 1- 17 for consideration upon entry of the present Amendment. The Applicant submits that claims 1 – 17 are in condition for allowance. Reconsideration and allowance of the claims is respectfully requested in view of the following remarks.

Claims Rejected under 35 U.S.C. 103(a)

Claims 1 – 17 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,264,610 to Zhu (Zhu) in view of U.S. Patent No. 6,185,320 to Bick et al. (Bick) (Office Action dated 06/08/2007, page 2)

In making the rejection, the Examiner has stated that

> Zhu fails to show, with respect to claims 1 and 10 segmenting the scanned volume into a lesion region including the lesion and a background region including the lesion and a background region absent the lesion using the ultrasound images ......., the value indicating lesion size is a value indicating a diameter of the lesion.

(Office Action dated 06/08/2007, page 4)

The Examiner has further stated that

> It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have combined the image segmentation technique as taught by Bick, in the device of Zhu, with the motivation that segmenting an mage will eliminate unnecessary components of the image (such as healthy tissue), sot that the important components of the image can be focused on (such as a lesion), increasing the chance of detecting cancer in the patient. There is a reasonable expectation of success to combine these references because both are related to imaging to detect breast lesions.

(Office Action dated 06/08/2007, page 5) Applicants respectfully disagree.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to

modify a reference or combined references; and that the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was make. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

The claimed invention is directed to scanning a subject with near infrared light and with ultrasound energy; segmenting a scanned volume obtained from the ultrasound image into a lesion region that includes a lesion and a background region that is devoid of the lesion; reconstructing from the optical measurements an optical image of at least a portion of the scanned volume, the reconstructing being performed using different voxel sizes for optical measurements corresponding to the lesion region and optical measurements corresponding to the background region. (see Claim 1)

Claim 10 differs from Claim 1 in that it additionally requires measuring parameters of the lesion using the ultrasound images to provide values indicative of the parameters; and reconstructing the optical image again using the values.

Zhu teaches a combined ultrasound and near infrared (NIR) diffused light imaging system includes a combined ultrasound and NIR light probe operatively connected to an ultrasound imaging system and an NIR diffused light imaging system. (see Abstract) Zhu teaches co-registering the images obtained from the ultrasound and the near-infrared light. (see Col. 6, lines 66 – Col. 7, line 1) Zhu teaches that co-registration of the ultrasound and the near-infrared images provide the benefits of optical contrast (from the near-infrared light) combined with the high resolution (from the ultrasound). Zhu however does not teach segmenting a scanned volume obtained from the ultrasound image into a lesion region that includes a lesion and a background region that is devoid of the lesion. Zhu additionally does not teach reconstructing from the optical measurements an optical image of at least a portion of the scanned volume, the reconstructing being performed using different voxel sizes for optical measurements corresponding to the lesion region and optical measurements corresponding to the background region. Zhu therefore does not teach all elements of the claimed invention.

The method outlined by Bick essentially comprises segmenting an image to distinguish the object from is surroundings to produce a segmented image, followed by performing

morphological operations for the detection of any enclosed lesions. (see Col. 2, lines 17 – 20) Bick teaches the detection of the enclosed lesions by filtering with a mass filter for the initial detection of circumscribed densities (see Col. 5, lines 66 – Col. 6, lines 15; see also Fig. 4), matching using a deformable shape template with Fourier descriptors (see Col. 6, lines 62 – Col. 8, lines 9, see also Fig. 6), optimization of the match using simulated annealing (see Col. 8, lines 4 – 17), and measuring the circularity and density characteristics of the suspected lesion (see Col. 9, lines 18 - 51).

In the first instance, Bick, like Zhu does not teach the claimed "segmentation". The segmentation disclosed by Bick is <u>not similar</u> to the presently claimed segmentation. The segmentation that is presently claimed requires classifying the scanned volume obtained from the ultrasound image into a lesion region that includes a lesion and a background region that is excludes the lesion. The segmentation is used to distinguish the lesion from the surrounding tissue.

In contrast, the segmentation disclosed by Bick is used for the determination of the boundary of the entire object (the tissue) present in an image. In this regard, Bick states:

> In the segmentation process, noise filtering is applied to the digital mammogram followed by application of the gray-value range operator. Using information from the local range operator a modified global histogram analysis is performed. Region growing is performed on the threshold image using connectivity (counting pixels), followed by a morphological erosion operation. The distance map of the image is determined and the boundary of the segmented object (breast) in the image is then tracked to yield its contour. The contour can then be output onto the digital image or passed to other computer algorithms.

(Col. 3, lines 51 – 61) Bick thus uses segmentation by using a grey value range operator to delineate the tissue (in this case, the breast) from the surrounding image and not the lesion from the surrounding tissue as presently claimed. The Examiner's contention that Bick teaches segmentation is therefore inaccurate.

Bick also does not teach reconstructing from the optical measurements an optical image of at least a portion of the scanned volume, the reconstructing being performed using different voxel sizes for optical measurements corresponding to the lesion region and optical measurements corresponding to the background region. Bick does not teach using voxels at all.

As noted above, Bick teaches lesion detection by filtering with a mass filter for the initial detection of circumscribed densities, matching using a deformable shape template with Fourier descriptors and optimization of the match using simulated annealing. Bick thus does not teach all elements of the claimed invention. Bick does not make up for the deficiencies of Zhu. Even if Bick were to be combined with Zhu, the combined invention would not be similar to the presently claimed invention.

In addition, one of ordinary skill in the art would not be motivated to modify Bick to arrive at the presently claimed invention. The method described by Bick uses images obtained from a single method. The presently claimed invention uses two types of images (ultrasound and near-infrared) for high contrast and optical resolution.

Since neither Zhu nor Bick teaches segmentation or using voxels of different sizes, Applicants believe that the Examiner has not made a prima facie case of obviousness over Zhu in view of Bick. Applicants respectfully request a withdrawal of the obviousness rejection over Zhu in view of Bick.

It is believed that the foregoing remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Assignee.

Respectfully submitted,

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